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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/820,339	03/29/2001	Sara Fuchs	FUCHS=2A	3100

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EXAMINER	
HAYES, ROBERT CLINTON	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 07/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/820,339	FUCHS ET AL.	
	Examiner	Art Unit	
	Robert C. Hayes, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 May 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-19,23-28,30 and 31* is/are pending in the application.

4a) Of the above claim(s) *10,11,13,23,24 and 26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8,9,14-19,25,27,28,30 and 31* is/are rejected.

7)☒ Claim(s) *12* is/are objected to.

8)☒ Claim(s) *8-19,23-28,30 and 31* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/14/04 has been entered.

2. The amendment filed on 5/27/04 has been entered.

3. Solely in the interest of customer service, Applicants are again reminded that this application contains claims 8i-ii, iv & viii-(in part), 9i-ii, (iv) & vi-vii-(both in part), 10-11, 13, *15-18 (in part)*, 23, 24, 26 & *30-31(in part)* that are drawn to inventions nonelected with traverse in Paper No. 10. A ***complete reply*** to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144), such as rewriting the claims to only the elected invention. See MPEP § 821.01. Failure to cancel nonelected claim segments or rewrite the elected claims to recite only the elected invention will be held as ***non-responsive*** to this office action, and may result in **ABANDONMENT** of this application. It is again noted that Applicants' arguments have already been addressed in Paper No: 11 (mailed 1/30/03), as it relates to the restriction requirement from Paper No: 9 (mailed 9/30/02). Second, in contrast to Applicants' assertions on pages 10-11 of the previous response, nothing in MPEP 803.4 requires

examination of "up to 10 sequences"; especially as it relates to structurally different sequences as illustrated by the unique SEQ ID NOs recited, which alternatively require their own individual search, for the reasons extensively made of record. Thus, the **restriction** requirement remains proper.

4. The rejection of claims 8-9, 12, 15-19 & 28-31 under 35 U.S.C. 112, first paragraph, as containing new matter for the recitation of "comprising residues 61-76 of SEQ ID NO: 2" is withdrawn due to Applicants' arguments. However, the second claim limitation in base claim 8 remains rejected as indicated below. It is further suggested that claim 28 be amended to actually recite the limitations of (vi) or (vii), in order to more clearly claim the invention.

5. The rejection of claims 12 & 14 under 35 U.S.C. 112, first paragraph, for lack of written description is withdrawn due to the amendment of the claims.

6. The rejection of claims 9, 12 & 14 under 35 U.S.C. 102(b) as being anticipated by Schoepfer et al is withdrawn due to the amendment of these claims to closed language. It is noted that although claims 8(vii) & 9(vii) have been obviated by the amendment to these particular claims due to Schoepfer disclosing the full length human acetylcholine receptor α subunit, the rejection for claims 8(vii) & 9(vii) may be re-instated upon the amendment of these claims to overcome the new matter rejection below.

7. The rejection of claims 12 & 14 under 35 U.S.C. 102(b) as being anticipated by Talib et al is withdrawn due to the amendment of these claims to closed language.

8. The rejection of claims 8-9, 12, 14, 16-19, 25, 27-28 & 30 under 35 U.S.C. 102(b) as being anticipated by Barchan et al. (1995; IDS Ref #AO) is withdrawn due to the amendment of the claims to no longer recite "fragments thereof", and because Barchan teach cloning the human AChR-α subunit for only encoded residues 212-205, as correctly argued by Applicants.

9. Claim 12 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

11. Applicants' arguments filed 2/05/04 & 5/27/04 have been considered but are not found persuasive.

12. Claims 8-9, 14-19, 27 & 30-31 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

application was filed, had possession of the claimed invention, for the reasons made of record in Paper No: 14 (mailed 10/14/03), and as follows.

No proper antecedent basis nor conception in context with that described within the specification at the time of filing the instant application exists for the different recitation of "comprising residues 184-210 of SEQ ID NO: 2" in base claim 8, as it relates to "suppresses the autoimmune response...". In contrast, only residues 61-76 of SEQ ID NO: 2 are described as "the main immunogenic region", whereas residues 184-210 are alternatively described as the "acetylcholine binding site", which is not reasonably involved in "suppressing an autoimmune response" as disclosed within the instant specification (i.e., as it relates to claims 8, 9, 14, 27 & 30); thereby, still constituting new matter.

No proper antecedent basis nor conception in context with that described within the specification at the time of filing the instant application exists for the new recitation of "wherein the human acetylcholine receptor α-subunit portion of said fused polypeptide *does not assume the native conformation of the α subunit of the human acetylcholine receptor*", etc. (i.e., as it relates to base claims 8vii & 9vii); thereby, constituting new matter.

13. Claims 8-9, 16-19, 25, 27-28 & 30-31 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons made of record in Paper No: 11 (mailed 1/30/03) & 14 (mailed 10/14/04), and as follows.

In contrast to Applicants' assertions, the claims remain not limited to encoded fusion polypeptides that increase "solubility" or create a "protease target sequence" for "further processing", etc. (e.g., see pg. 30 of the specification), in which no specific DNA sequences encoding any putative fusion sequence are described (i.e., as it relates to claims 8(vii), 9(vii), 19 & 30). Nor are any different open reading frames that merely "comprise" the recited fragments of SEQ ID NO: 1 described, which by themselves do not constitute an open reading frame (e.g., as it relates to claims 8 (iii)(v)(vi)(vii), 9(vii), 25, 27-28 & 30-31), as previously made of record; consistent with that held by the courts in *Fiers v. Revel,* and *Univ. California v. Eli Lilly and Co.,* previously made of record. In other words, base claim 8 still recites open claim language for a "DNA molecule coding for a polypeptide... *comprising* residues... wherein said polypeptide *comprises* a human acetylcholine receptor...", versus a "DNA molecule consisting of a sequence that encodes a polypeptide...", etc. (e.g., as it relates to claim 8, 25, 27, 28 & 30). See MPEP 2163.

14. Claims 9(vi) is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is ambiguous what the claim language of "a DNA molecule which is degenerate as a result of the genetic code, to any DNA sequence of (i) to (v) and which codes..." is suppose to distinguish within the claim, when any DNA that encodes a polypeptide encompasses any

degenerate DNA molecule, by definition. It is suggested that claim 9(vi) be amended to delete the underlined redundant claim language to more clearly claim the instant invention.

15. Claims 8 & 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, because the recitations of "a polypeptide as defined in... (vi)" and "the polypeptide Hα1-210 of SEQ ID NO: 2" recite the same claim limitation in single claim 8(vii); thereby, appearing duplicative and/or otherwise confusing.

Claim 9 is indefinite because Markush group (iv) is no longer recited in claim 9, yet the claims 9(vi) & (vii) depend on this apparently cancelled/withdrawn part of claim 9.

16. Claims 15 & 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, because although the addition of GST to the DNA molecules encoding fusion polypeptides of base claim 8 or 9 would partially overcome the new matter rejection above, it is contradictory and confusing whether such a molecule would "not assume the native conformation of the α subunit of the human acetylcholine receptor" once encoded, as currently claimed.

17. Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as

the invention, because the recitation of "a fused polypeptide" appears to lack proper antecedent basis in the majority of the recited Markush group in base claim 8, in which only base claim 8(vii) recites the limitation of a "fusion polypeptide"; thereby, confusing what exactly claim 19 is suppose to entail, especially when the metes and bounds encompassed by this recitation are unknown and not definitively described within the specification.

18. Claims 8, 16-19, 27-28 & 30 stand rejected under 35 U.S.C. 102(b) as being anticipated by Schoepfer et al. (1988), for the reasons made of record in Paper No: 11 (mailed 1/30/03) & 14 (mailed 10/14/04), and as follows.

In contrast to Applicants' arguments on page 13 of the response, the claims still recite open claim language for a "DNA molecule coding for a polypeptide... *comprising* residues... wherein said polypeptide *comprises* a human acetylcholine receptor...", versus a "DNA molecule consisting of a sequence that encodes a polypeptide...". Thus, Applicants' arguments are moot.

19. Claims 8-9, 16-19, 25, 28 & 30 stand rejected under 35 U.S.C. 102(b) as being anticipated by Talib et al. (1991; IDS Ref #AM), for the reasons made of record in Paper NOs: 11 (mailed 1/30/03) & 14 (mailed 10/14/04), and as follows.

In contrast to Applicants' arguments on pages 13-14 of the response, the claims still recite open claim language for a "DNA molecule coding for a polypeptide... *comprising* residues... wherein said polypeptide *comprises* a human acetylcholine receptor...", versus a "DNA molecule consisting of a sequence that encodes a polypeptide...", etc. It is further noted that the sole difference between Talib's sequence and DNA encoding Hα1-210 of claims 8(vi) & (vii), 9(vii),

25, 28 & 30 is the mere addition/fusion of the Met start codon residue at the N-terminal end of SEQ ID NO: 2, which is inherently removed during proteolytic processing of eukaryotic proteins, in which this fusion polypeptide of Talib also inherently "does not assume the native conformation of the α subunit of the human acetylcholine receptor" because Talib's polypeptide constitutes a truncated version of the human acetylcholine receptor. Thus, Applicants' arguments are not persuasive.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (571) 272-0885. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961. The fax phone number for this Group is (703) 872-9306.

Robert C. Hayes, Ph.D.
July 19, 2004

ROBERT C. HAYES, PH.D.
PATENT EXAMINER